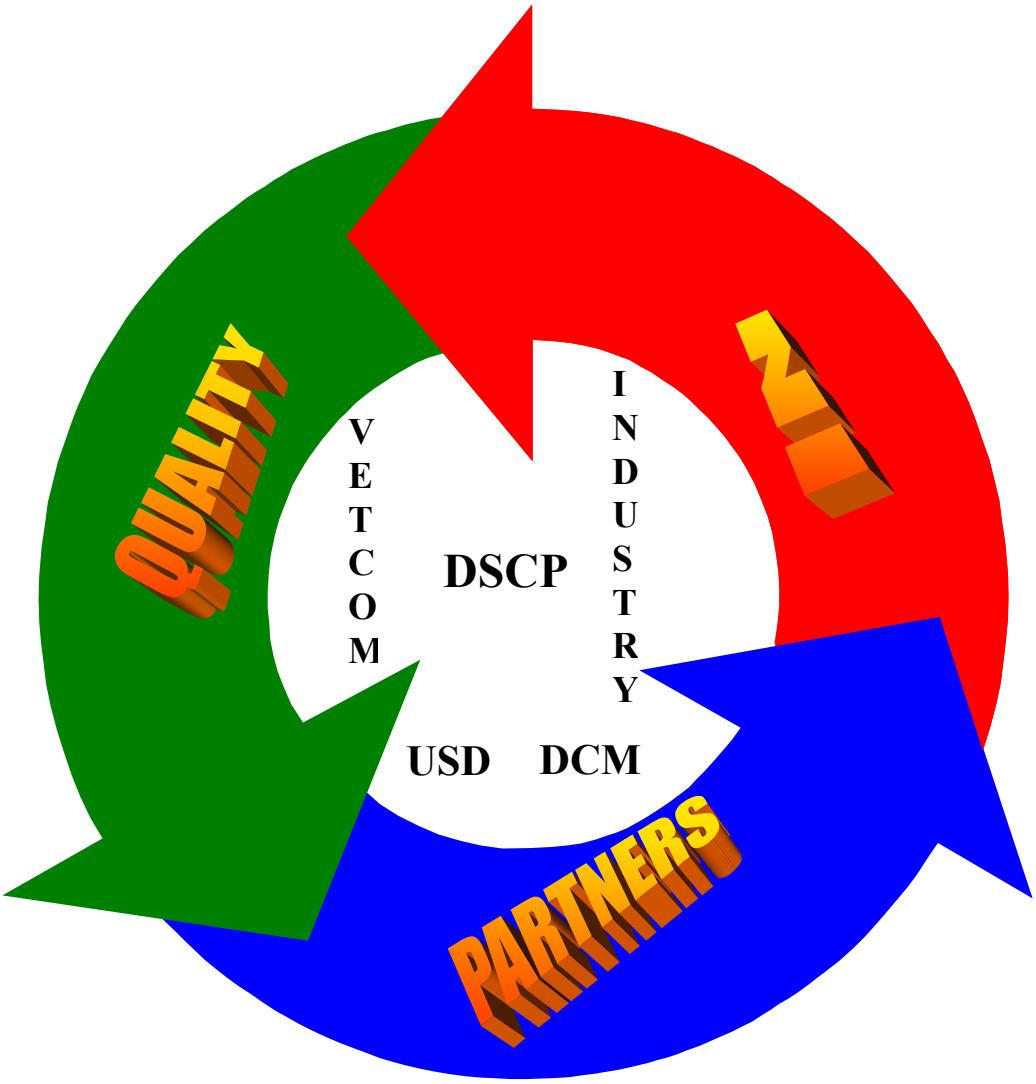
DEFENSE SUPPLY CENTER PHILADELPHIA
DIRECTORATE OF SUBSISTENCE
OPERATIONAL RATIONS



QUALITY SYSTEMS AUDIT
WORKBOOK I
DOCUMENTED QUALITY SYSTEMS PLANS (QSP)
EVALUATION GUIDELINE

August 2004
Revision 3

FORWARD

The Quality Standard ANSI/ISO/ASQ Q9001-2000 Quality Management Systems -Requirements, which replaced ISO 9001:1994, ISO 9002:1994, and ISO 9003:1994, is the quality standard referenced in the current operational Rations contracts/Technical Data Packets. This standard, ANSI/ISO/ASQ Q9001-2000, is applicable to suppliers required to submit a documented Quality System Plan (QSP) and performing under the higher-level contract quality requirements. Documented QSPs modeled using ISO 9002:1994 should reference the new standard, ANSI/ISO/ASQ Q9001-2000. Suppliers that currently have a QSP rated acceptable and are successfully performing under the higher-level contract quality requirements should have no difficulties making the transition, with minor changes, from ISO 9002:1994, to the new standard, ANSI/ISO/ASQ Q9001-2000.

This workbook was developed using the guidance and requirements of the following documents: ANSI/ISO/ASQ Q9001-2000 Quality Standard; DLAR MPC Clause 52-246-9001 Manufacturing Process Controls and In-Process Inspection; Statistical Process Control Quality Assurance Provision (SPC QAP); ANSI/NCSL Z540-1 and ISO 10012-1 Control of Inspection, Measuring, and Test Equipment, and; general requirements cited in the Operational Rations Technical Data Packets (TDP) specifying Higher Level Contract Quality requirements. The workbook was developed to ease the transition to the new standard and to standardize the evaluations of documented QSPs developed using ANSI/ISO/ASQ Q9001-2000, other recognized industry quality standards, or a non-standard supplier's specific process control system. When the Higher Level Contract Quality requirements are cited in the contract, suppliers are to clearly specify their preferred documented quality system in accordance with ANSI/ISO/ASQ Q9001-2000, a system that meets other recognized industry quality standards, or a process control system that is equivalent to or better than ANSI/ISO/ASQ Q9001-2000. If the supplier proposes an alternate (i.e., non-standard) process control system, this shall be clearly stated in the QSP. Regardless of the standard or non-standard document used to model the QSP, the QSP shall address, at a minimum, the elements cited in the contract and, within each element, the supplier shall provide the information requested in each section of this workbook.

This revision contains the following significant change:

1. Section V Handling, Storage, Packaging, and Delivery Program, Product Identification and Traceability Program, Control of Nonconforming Product, and Organization/Corporate Security Plan: This section was renamed Control and Protection of Product and Food Security. The goal was aimed in reducing title size.

2. The Inspection and Test Status and Records requirements previously cited in three different sections (Receipt inspection, In-Process and Process Inspection, and End Item Inspection) were moved to Section V. The goal was aimed in reducing duplication.

3. Section X Statistical Process Control was combined with other sections as follows: Area 1 and 2 were combined with Section I; area 3 was combined with Section II; area 4 was combined with Section VI; areas 5 and 6 were combined with Section VIII; area 7 was (previously) combined with each applicable section of the workbook. The goal was aimed in reducing duplication.

To download a copy of this guideline go to http://www.dscp.dla.mil/subs/oprat.htm or contact the applicable PCO or the Operational Rations Unit, Product Quality Office. Beneficial comments (recommendations, additions, deletions) and any pertinent data which may be used in improving this document should be addressed to: Defense Supply Center Philadelphia, Directorate of Subsistence, Bldg. 6, ATTN: DSCP-HROS, 700 Robbins Street, Philadelphia, PA 19111-5092. Fax (215) 737-0379

or Voice (215) 737-8656/3876

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LIST OF TERMS, ABBREVIATIONS AND ACRONYMS

1. ANSI: American National Standards Institute.
2. ASQC: American Society of Quality Control.
3. CAR: Corrective Action Request.
4. CFR: Code of Federal Regulations.
5. DFAR: Defense Federal Acquisition Regulation.
6. DLA: Defense Logistics Agency.
7. DLAM: Defense Logistics Manual.
8. DLAR: Defense Logistics Regulation.
9. DSCP: Defense Supply Center Philadelphia.
10. FAR: Federal Acquisition Regulation.
11. FDA: Food and Drug Administration.
12. HACCP: Hazard Analysis Critical Control Point.
13. IPMSP: Integrated Pest Management and Sanitation Program.
14. ISO: International Organization for Standardization.
15. LCL: Lower Control Limits.
16. LSP: Lower Specification Limits.
17. MPC: Manufacturing Process Controls.
18. QA: Quality Assurance.
19. QAP: Quality Assurance Provision.
20. QAR: Quality Assurance Representative.
21. QAS: Quality Assurance Specialist.
22. QC: Quality Control.
23. QIIR: Quality Initiative Report.
24. QS: Quality System.
25. QSP: Quality System Plan.

26. SPC: Statistical Process Control.
27. TDP: Technical Data Package.
28. UCL: Upper Control Limits.
29. USDA: United States Department of Agriculture.
30. USDA-AMS: USDA Agricultural Marketing Services.
31. USDA-FSIS: USDA Food Safety Inspection Services.
32. USL: Upper Specification Limits.
33. VECP: Value Engineering Change Proposal Program.
34. VETCOM: Veterinary Command.

GENERAL QUALITY SYSTEMS PLAN AND QUALITY SYSTEMS REQUIREMENTS (ISO 9001:2000 ELEMENTS 1 – 3 AND SECTION E OF THE TDP)

1. SCOPE

1.1. GENERAL: This workbook was developed using the guidance and requirements of the following documents: ANSI/ISO/ASQ Q9001-2000 Quality Management Systems- Requirements; DLAR MPC Clause 52-246-9001 Manufacturing Process Controls and In-Process Inspection; Statistical Process Control Quality Assurance Provision (SPC QAP); ANSI/NCSL Z540-1 or ISO 10012-1 Control of Inspection, Measuring, and Test Equipment, and; general requirements cited in the Operational Rations Technical Data Packets (TDP) specifying Higher Level Contract Quality requirements. The workbook was developed to standardize the evaluations of documented Quality Systems Plans (QSPs) developed using ANSI/ISO/ASQ Q9001-2000, other recognized industry quality standards, or a non-standard supplier's specific process control system.

1.2 APPLICATION: When the Higher Level Contract Quality requirements are cited in the contract, suppliers are to clearly specify their preferred documented quality system in accordance with ANSI/ISO/ASQ Q9001-2000, a system that meets other recognized industry quality standards, or a process control system that is equivalent to or better than ANSI/ISO/ASQ Q9001-2000. If the supplier proposes an alternate (i.e., non-standard) process control system, this shall be clearly stated in the QSP. Regardless of the standard or non-standard document used to model the QSP, the QSP shall address, at a minimum, the elements cited in the contract and, within each element, the supplier shall provide the information requested in each section of this workbook. Documented QSPs are submitted by suppliers for the purpose of demonstrating their capability to meet the higher-level contract quality requirements and for Procurement Contracting Officers (PCO) to assess a supplier's capability to meet these requirements. The Government will recognize a supplier's quality system whenever it meets the contract requirements, whether the quality system is modeled on military, commercial, national or international quality systems standards. The design and implementation of a QSP will be influenced by the varying needs of a company, its particular goals and objectives, the products produced, and the processes and specific practices employed in the operation. The intent of the requirements is for suppliers to improve process capability, process control which, when used effectively, can result in a prevention-oriented approach rather than a detection approach that will improve product quality and lower cost through a single quality system in any supplier facility. Suppliers are required to establish, document, submit for Government evaluation, and maintain a quality system as a means of ensuring that product conforms to the requirements of the contract. However, it should be emphasized that the quality system requirements cited in the selected standard/non-standard document are complementary (not alternative) to the contract specified requirements.

2. NORMATIVE REFERENCE:

A. The documented QSP shall include the quality system procedures, reference or include working instructions and forms, and outline the structure of the documentation used in the quality system. The Higher Level Contract Quality Requirements (HLCQR), MPC Clause, SPC QAP apply to all operational rations Contractor-Furnished Material (CFM) and Government-Furnished Material (GFM) food components and Sub Assembly and Assembly Operations, unless specifically excluded in the contract (only the SPC QAP is entirely excluded from some contracts and for some components in some contracts). However, regardless of the standard or non-standard document used to model the QSP, if the QSP satisfactorily addresses, at a minimum, the elements cited in the contract and, within each element, the supplier submit the required documentation and provides the information requested in each section of this workbook, the supplier's QSP will be demonstrating their capability to meet the higher-level contract quality requirements, the requirements cited in ISO 9000:2000, MPC Clause, and the SPC QAP. Redundant areas/requirements (cited in the MPC Clause or the SPC QAP) need only be addressed once in the QSP and must encompass the requirements of the most stringent document. The calibration of measuring and testing equipment shall, as a minimum, adhere to the requirements of ANSI/NCSL Z540-1 or ISO 10012-1 (supplier must identify the document selected for the calibration system). The quality manual (QM) or QSP submitted must include the documents requested (working instructions, forms/containing instructions, lists, etc.) or other applicable secondary documents (regardless of QM or QSP's tier) and satisfactorily answer the questions in this workbook, in order to receive an acceptable rating.

It is strongly recommend, that in addition to the QSP, contractors also maintain a copy of all ancillary documents (procedures, working instructions, forms, reports, lists, etc.) submitted with the QSP and that resulted in the initial QSP receiving an acceptable rating. If a new QSP is developed or revised, the additional documents originally submitted with the QSP, must be submitted with the new QSP or anytime these ancillary documents are revised. Failure to submit revised documents may result in the acceptability of the QSP to be withdrawn or the new/revised QSP to be rated unacceptable.

A DSCP Quality System Qualification Certificate will be issued once the supplier's QSP is rated fully acceptable and a Government Quality System Compliance Audit has been conducted to verify the implementation and compliance of the approved QSP and the effectiveness of the system implemented in consistently producing conforming product. The acceptability of the QSP and the quality system qualification may be withdrawn under the following circumstances and/or as indicated in the contract: The supplier fails to implement and comply with the approved QSP; fails to submit QSP revisions for Government review and approval (as indicated in the contract); and/or fails to make changes to the QSP when this is no longer effective or the system implemented is not capable of consistently producing conforming product.

B. Documented QSPs will be evaluated by the Operational Rations CBU Product Quality Office, Quality Systems Audit Team, the Operational Rations Coordinators from each respective inspection office (USDA-AMS/VETCOM/DCMA) and the Government In-Plant QARs assigned to perform Government QA functions at the supplier's plant. Aforementioned Government personnel will use this evaluation guideline (in conjunction with the standard or other documents identified in the supplier's QSP and other general requirements cited in the TDPs), as the basic framework against which they will evaluate documented QSPs.

C. This workbook is divided into 13 sections. Note that Section XIII Improvement is a requirement not an option. The language cited in this section contains requirements cited in element 8 of ANSI/ISO/ASQ Q9001-2000 and the Operational Rations TDP (this language was previously optional under ISO 90002-1994 and the TDP). Each section of the workbook contains the applicable reference document: The applicable elements of ANSI/ISO/ASQ Q9001-2000; MPC Clause; SPC QAP; ANSI/NCSL Z540-1 or ISO 10012-1; Code of Federal Regulations, and; other general requirements cited in the Operational Rations TDPs. If additional information or clarification is necessary, the referenced documents shall be consulted or DSCP-HROS contacted at the address or phone numbers listed in page i.

NOTE: TO THE EXTENT OF ANY INCONSISTENCY BETWEEN THE CONTRACT OR ITS GENERAL PROVISIONS AND A SUPPLIER'S QSP, THE QUALITY STANDARD SELECTED, THIS WORKBOOK, AND/OR IMPLEMENTED QUALITY SYSTEM, THE CONTRACT AND THE GENERAL PROVISIONS SHALL CONTROL.

SECTION I

MANAGEMENT RESPONSIBILITY AND QUALITY SYSTEM DESIGN

REFERENCE: Contract TDP Section E, MPC Clause, SPC QAP, Specific Product Specifications or Commercial Item Descriptions, ISO 9001:2000 (4,4.1, 4.2.1, 4.2.2, 5, 5.1,5.3, 5.4.1, 5.5, 5.5.1, 5.5.2, 5.6, 6, and 6.2) and ANSI/ASQC Z1.4.

	Max Points	Assigned

AREA 1. MANAGEMENT RESPONSIBILITY (ISO 5):

A. QUALITY POLICY (ISO 5.1, 5.2, 5.3, and 5.4.1):

1. Are the company's policy, objectives, and commitment to quality identified?

2. If statistical process control techniques are used, does the QSP identify the policy for applying SPC and the goals and commitments for using SPC?

3. Is the company's policy relevant to the overall organizational goals and the expectations and needs of the Government?

4. Does the QSP identify how top management ensures that the quality policy is communicated, understood, and maintained at all levels of the organization?

B. ORGANIZATION (ISO 5.5 and 5.5.1):

1. Responsibility and authority: Specific names of individuals do not have to be provided as long as the positions are identified. An organization chart must be included to illustrate and explain the relationship of the quality assurance (QA) and production personnel to the rest of the organization and the assignment and responsibilities of QA and production personnel within the organization:

a. Was a copy of the organization chart included?

b. Does the chart clearly illustrates and identifies the relationship of quality to production personnel?

c. Is the relationship of quality and production to the overall organization clearly identified?

2. Resources requirements (ISO 6 and 6.2):

a. Does the QSP identify management personnel (by position and assignment) responsible for the overall implementation and effectiveness of each section of the QSP?

b. Does the QSP identify the assignment of trained personnel responsible for the supervision, performance of work, and verification activities such as inspection and testing at each location identified in the QSP?

3. Management Representative (ISO 5.5.2): Does the company identify the manager(s), irrespective of other responsibilities, who have the defined authority for: (1) Ensuring that the quality system is established, implemented, and maintained in accordance with the quality standard selected and the contract specified quality requirements; (2) reporting on the performance of the quality system to the company's top management for review and as the basis for improvement of the system, and or; (3) represent the company as a liaison between the contractor and DSCP on matters relating to the company's quality system?

C. MANAGEMENT REVIEW (ISO 5.6):

1. Does the company's identify the manager, with executive responsibility, who is responsible for reviewing the quality system to ensure its continuing suitability and effectiveness in satisfying the requirements of the quality standard selected, the company's stated quality policy and objectives, and the requirements of DSCP contracts?

SECTION I Continued

	Max Points	Assigned
2. Is the interval for management's quality system review defined?		
3. Is the interval sufficient to meet the requirements of the standard selected, contract requirements, and company's stated quality policy and objectives? The frequency shall not be less than the frequency of DSCP's compliance audits for a contractor's facility (at least annually).		
4. Does the company indicate the type of records to be maintained for the management reviews?		
AREA 2 QUALITY SYSTEM (ISO 4): The information required in this area needs to be evaluated after all other sections of the QSP are evaluated.		
A. QUALITY SYSTEM DESIGN (ISO 4, 4.1, and 4.2.1):		
1. Is the quality standard used to develop the QSP identified (if a non-standard document was used or if the supplier used this guideline, workbook I, to develop their QSP, this must clearly be indicated in the QSP).		
2. Does the QSP, at a minimum, cover the elements cited in the contract TDP?		
B. QUALITY SYSTEM PROCEDURES (ISO 4.2.2):		
1. Does the QSP include procedures covering the quality system implemented as a means of ensuring product conformance to contract requirements? **NOTE:** The quality manual (QM) or QSP submitted must include the documents requested (working instructions, forms/containing instructions, lists, etc.) or other applicable secondary documents (regardless of QM or QSP's tier) and satisfactorily answer the questions in this workbook, in order to receive an acceptable rating. The contractor shall maintain a copy of all ancillary documents (procedures, working instructions, forms, reports, lists, etc.) submitted with the QSP and that resulted in the initial QSP receiving an acceptable rating. If a new QSP is developed or revised, the additional documents originally submitted with the QSP, shall be submitted with the new QSP or anytime these ancillary documents are revised. Failure to submit revised documents may result in the acceptability of the QSP to be withdrawn or the new/revised QSP to be rated unacceptable.		
2. Are the procedures consistent with the requirements of the quality standard selected and the requirements of the contract?		
3. If the working instructions (that define how each activity is performed) and forms used were not included with the QSP, are these identified in the document master list and referenced in the documented procedures?		
C. QUALITY PLANNING (ISO 5.4.1):		
1. Does the QSP clearly define how the requirements for quality will be met?		
2. Is the QSP consistent with the company's policy and quality objectives, documented to suit the company's method of operations, and the requirements of the contract?		
TOTAL POINTS :	**100**	

SECTION I AUDITOR'S NOTES (justification/comments must be provided for areas/questions found marginally acceptable, unacceptable or not addressed) :

SECTION II
TRAINING

REFERENCE: Contract TDP Section E, MPC Clause, SPC QAP, CFR, and ISO 9001:2000 (6.2.2)

	Max Points	Assigned

GENERAL: The contractor shall establish and maintain documented procedures for identifying training needs and provide the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and or experience, as required by the contract, regulatory agency, and company for each position. Copy of records (certificates, diplomas, other record of attendance of internal or external training) shall be maintained for each employee.

A. **Training Manager**: Does the QSP identify the company's manager (by position) responsible for the overall implementation and effectiveness of the contractor's training program and the person responsible for maintaining training records?

B. **Training and Qualification Requirements:**

1. **Supervisory Personnel**: Does the QSP identify the training/qualification requirements for supervisory personnel (by position as identified under resource requirements) responsible for ensuring implementation compliance and effectiveness of the quality systems program (covering the 13 areas of the QSP)?

2. **Non-supervisory personnel:** Does the QSP identify the qualification and training requirements for personnel (by position/grouping of positions) performing inspections, testing, monitoring, and recording the following activities (as applicable to the assigned position): document and data control; Integrated Pest Management and Sanitation Program; handling, storage, packaging, preservation, and delivery program; product identification and traceability; control of nonconforming material; contract reviews and purchasing; receipt inspection and testing; in-process and process inspection and testing; regulatory requirements and controls; statistical process controls; end item inspection and testing; internal audits; and corrective and preventive actions.

3. **Regulatory/Contractual Training Certification Requirements:** Does the QSP identify personnel by position required by regulatory agencies, contract and/or the contractor to be certified or trained in a specific technical skill (e.g., Processing Authority, retort supervisors, retort operators, HACCP manager, container integrity/can seam technicians, water treatment technicians, sanitation personnel, pest management personnel, etc.)?

4. **Compliance with Training Certification Requirements:** Does the QSP identify the steps to be taken to ensure personnel (responsible for performing, monitoring or ensuring compliance to regulatory requirements) obtain the required certifications/qualifications for each position identified above (training may be the same for same or similar positions)?

C. The QSP must identify the following for each section or quality activity identified above and/or in other areas of the QSP: (same or similar jobs may be grouped together if the training requirement is the same):

1. Who will be trained (by position)?

2. How much training is planned (new employees and current employees)?

3. Types and extent of training (academic, On-the-Job-Training, or combination).

4. Who will conduct the training and where will the training take place (internal or external source)?

TOTAL POINTS :	**100**	

SECTION II AUDITOR'S NOTES (justification/comments must be provided for areas/questions found marginally acceptable, unacceptable or not addressed) :

SECTION III
DOCUMENT AND DATA CONTROL AND CONTROL OF QUALITY RECORDS

REFERENCE: Contract TDP Section E, MPC Clause, SPC QAP, Specific Product Specifications or Commercial Item Descriptions, and ISO 9001:2000 (4.2, 4.2.1, 4.2.3 and 4.2.4).

	Max Points	Assigned
GENERAL: The contractor shall establish and maintain documented procedures to control all records and documents related to the requirements of the quality standard selected and the contract requirements. The procedure must also include control of documents of external origin such as commercial or Government standards, specifications, regulations, other documents, and all data generated by the quality system.		
AREA 1. DOCUMENT AND DATA CONTROL (ISO 4.2.1 and 4.2.3):		
A. Does the QSP include a master list or equivalent document-control procedure identifying the current revision status of documents being used by the company (procedures, working instructions, forms, reports or other documents)?		
B. Does the QSP state how documents and data are reviewed and approved for adequacy prior to issue?		
C. Does the QSP indicate how the contractor ensures the appropriate documents (procedure, working instructions, specifications, contract, or other documents) are available at all locations where operations essential to the effective functioning of the quality system are performed?		
D. Does the procedure ensures against the unintended use of invalid and or obsolete documents at all points of issue or use?		
E. Does the QSP indicate that changes to documents shall be reviewed and approved using the same procedure and by the same function that performed the original review and approval? If not, the plan should specifically designate otherwise.		
AREA 2. CONTROL OF QUALITY RECORDS (ISO 4.2.4): The contractor shall establish and maintain documented procedures for the identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records and other records generated by the system.		
A. Does the procedure indicate how records will be identified/collected/ indexed/filed (e.g., by product, lot number, production date, etc.)?		
B. Does the procedure indicate how and where (internal/external location) records will stored/ maintained? Based on the storage location identified, does it appear that records can be readily retrievable? NOTE: Ready retrievable is defined as retrievable within 1 day (24 hours) of request during an audit or in the case of a hazardous food recall.		
C. Is the storage facility identified (location of storage) suitable to prevent damage or deterioration and to prevent loss of records?		
D. Retention period and review: Does the record retention procedure indicates that all records, documentation pertaining to DSCP contracts will be retained and be available for review and evaluation by Government personnel during production of the contract and for a period of three years after completion of the contract or as indicated in the contract?		
TOTAL POINTS:	**100**	

SECTION III AUDITOR'S NOTES (justification/comments must be provided for areas/questions found marginally acceptable, unacceptable or not addressed)

SECTION IV

CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENTREFERENCE: Contract TDP Section E, MPC Clause, SPC QAP, ANSI/NCSL Z540-1 or ISO 10012, and ISO 9001:2000 (7.6)

	Max Points	Assigned

GENERAL: The contractor shall establish and maintain documented procedures to control, calibrate, and maintain inspection, measuring, and test equipment and measuring devices used by the company to demonstrate the conformance of product to requirements of the contract and the contractor's QSP requirements. The procedures must be developed based on the requirements cited in ANSI/NCSL Z540-1 or ISO 10012-1 (the document selected must be identified) and other requirements of the contract as applicable.

A. **Calibration Master List:** Does the QSP include a clear and complete calibration program that complies with the above documents for all inspection, measuring and test equipment? A master list of all measurement and test equipment that will be used for all inspections and testing activities and indication whether the equipment needs calibration, adjustment or maintenance must be included with the QSP. **NOTE:** Although the current calibration dates are not required to be reflected on the list, the list must, at a minimum, contain the following (a revised list needs to be submitted when a new piece of equipment is added or deleted or calibration frequencies are changed):

1. List of all equipment (by description) that require calibration/certification.

2. List of standards (test weights, certified thermometers, etc.) used to perform internal calibrations and/or pre-operational checks on equipment.

3. Identification (serial number/other ID) of each piece of equipment and standard listed.

4. Calibration frequency for equipment (and standard calibration/certification frequency) and who performs the calibration for each piece of equipment (internal or external source).

5. If a pre-operational check is conducted, identify the frequency and acceptable calibration tolerance for each piece of equipment that requires a pre-operational check.

6. Location of equipment (if not at same location indicate portable).

Example of List

Equipment	Serial # or ID #	Calibration frequency	Performed by	Pre-op frequency	Performed by	Standard Used	Location	Internal Procedure
O'Haus Scale	XXX	Quarterly	External	Prior to use	QA	100 grams	Portable	QAI-01 Rev B
Dial thermometer	1	Prior to use	QA	N/A	N/A	MIG I	Receipt	QAI-02 Rev C
MIG Thermometer	3	Annually	External	N/A	N/A	See certificate	Retort # 1	See certificate

Standards	ID #	Calibration frequency	Performed by	Location	Standard
MIG thermometer	1	Annually	External	QA Lab	See Certificate
Test weight set (100gr-500gr)	1	*Certified	External	QA Lab	See certificate
Test weight 25 Lbs	3	*Certified	External	Receipt	See certificate

***Replaced or re-certified if damaged**

B. **Procedures/Documentation:** Does the QSP provide for complete documentation of the calibration program (references or includes procedures, working instructions and forms or reports used to insure all required information is properly documented and records are maintained)?

1. For each piece of equipment or grouping of equipment (e.g., scales, thermometers) that requires calibration, pre-operational check, adjustment, maintenance, as applicable, the procedures shall include the following: The reference to the applicable calibration instruction/procedure for internal calibrations or pre-operational checks conducted or the procedure itself, acceptable calibration tolerance for each piece of equipment that requires a pre-operational check or calibration, and measurement standard that applies. **Note:** This information may be included on the master list.

SECTION IV Continued

	Max Points	Assigned
2. Does the QSP requires that operators perform a pre-operational check to ensure equipment is functional and within tolerance?		
3. Does the QSP indicates how and when (frequency) the seal bars for each sealing machine/ seamer are checked? Does the QSP identifies the temperature requirements to obtain an acceptable seal (temperature range) and form used to record results. NOTE: The DoD Task Force of 1986 identified not checking the seal bars as a major weakness in the system and a possible contributor to flexible pouches seal problem.		
4. Does the QSP indicate that all measuring and test equipment and measurement standards will be labeled to indicate calibration status (the calibration sticker attached to of each piece of equipment/standard must identify the date calibration was performed, next calibration due date, and who performed the calibration).		
5. Does the QSP include a procedure to recall equipment that is due for calibration (for example, how the contractor ensure each piece of equipment is calibrated at the established interval)?		
6. Does the QSP include a procedure for identification and prevention from use of faulty equipment? **NOTE:** Faulty equipment shall be tagged/labeled.		
C. Does the QSP stipulate the contractor will make available all measuring and test equipment required by the Government QAR to perform Government verification inspections at the contractor or subcontractor's facilities and upon request make personnel available for operation of such equipment?		
TOTAL POINTS:	**100**	

SECTION IV AUDITOR'S NOTES (justification/comments must be provided for areas/questions found marginally acceptable, unacceptable or not addressed)

SECTION V
CONTROL AND PROTECTION OF PRODUCT AND FOOD SECURITY

REFERENCE: Contract TDP Section E, MPC Clause, SPC QAP, Specific Product Specifications or Commercial Item Descriptions, and ISO 9001:2000 (7.5.3, 7.5.5, and 8.3) and ANSI/ASQC Z1.4.

	Max Points	Assigned
AREA 1. HANDLING, STORAGE, PACKING, PACKAGING, PRESERVATION, AND DELIVERY PROGRAM (ISO 7.5.5):		
A. Does the QSP include a procedure that identifies the methods for the handling, preservation, and protection of product and packaging materials (especially packaging that comes in direct contact with the product) to prevent its contamination, cross-contamination, or damage during production or clean-up?		
B. Does the QSP include a procedure that identifies the designated areas or stock rooms and the methods of storing product and packaging materials (especially packaging that comes in direct contact with the product) to prevent contamination, cross-contamination, damage or deterioration of product/materials pending use, storage, or delivery?		
C. Does the QSP include a procedure that identifies the appropriate methods used for authorizing receipt and release of product/ingredients/materials from storage areas?		
D. Does the QSP include a procedure that identifies an appropriate interval to assess the condition of product in stock to detect damage or deterioration?		
E. Does the QSP include a procedure that identifies the methods to control packing, packaging and marking processes (including materials used) to ensure conformance to contract requirements?		
AREA 2. PRODUCT IDENTIFICATION AND TRACEABILITY (ISO 7.5.3):		
A. Does the QSP include a procedure for identifying product from receipt and during all stages of production, assembly, and delivery?		
B. Does the QSP include a procedure for unique identification of individual products or batches?		
C. Does the QSP include a procedure for hazardous food recalls mandated by Government regulatory agencies or for contractor's voluntary recalls of products found to be nonconforming with contract requirements or posing a potential health hazard to the consumer?		
D. Does the QSP indicates if mock test recalls are conducted to test the effectiveness of the contractor's food recall program? If no, do the QSP indicates how do the contractor measure the effectiveness of their recall capability?		
AREA 3. INSPECTION AND TEST STATUS AND RECORDS (ISO 4.2.3, 4.2.4 and 7.5.3):		
A. Inspection and test status (applicable to all stages of the processes describe in Section VII, VIII, IX, and X):		

	Max Points	Assigned

1. Does the QSP describe the methods used to identify and maintain the inspection status (conforming or nonconforming) of ingredients/components/ materials throughout the process (from receipt to finished product) to ensure only conforming ingredients/components/materials are released for production/ assembly, and only conforming product is released for shipment?

2. Does the QSP provide for an adequate method to place product on hold until all the required inspections and tests have been completed or necessary reports or approvals have been received and verified by authorized personnel prior to releasing ingredients/components/ materials for production/assembly and/or end item lots for shipment?

B. Inspection and test records (ISO 4.2.3 and 4.2.4):

1. Does the QSP contain procedures and indicate that records must be established and maintained to provide evidence that the end item lot has been inspected and tested and that it has passed the contractor's end item inspection based on the defined acceptance criteria cited in the contract (prior to submitting the lot for Government verification inspection)?

2. Does the QSP stipulate that if a product fails any inspection, the nonconformance requirements cited in the contract, as applicable, and the procedures for control of nonconforming product shall apply?

3. Does the QSP identify the person (maybe different positions) with the authority for the release of ingredients/components/materials during receipt, storage, production, assembly, and/or shipment?

AREA 4. CONTROL OF NONCONFORMING PRODUCT (ISO 8.3):

A. Does the QSP include a procedure to prevent the unintended use of ingredients or assembly of product that does not conform to specified contract requirements, pending test or inspection results, or other contractor's requirements? **NOTE:** Pallets/cases of items placed on hold (for any reason) must be prominently marked or tagged with hold tags. Hold tags shall include, at a minimum, the following information: Identification of the item; lot number/subcodes if applicable; quantity (case quantity and/or partial case quantities); reason for hold; and date placed on hold. All items placed on hold must (as much as possible) be maintained together and each pallet must be tagged. As an option, if pallets are maintained together, pallets can be cordoned-off with caution tape (or other appropriate tape) and one tag placed on front of the pallets.

B. Does the QSP provide an effective system to identify the inspection status (conforming or nonconforming) of components and materials and is system distinctly different from the Government's identification system? **NOTE:** Product found nonconforming by the contractor's inspection system must be tagged by the contractor with contractor's tags. Product found nonconforming by the GQAR's during a Government verification inspection must be tagged with a Government tag by the GQAR (with contractor's personnel assistance). Only a GQAR is authorized to remove Government tags.

C. Hold record/log: Does the procedure provide for the identification, documentation, evaluation, segregation, and disposition of nonconforming product? **NOTE:** The contractor must develop and maintain a running record/log of ingredients/products/materials placed on hold (by the contractor or the GQAR). This record/log must, at a minimum, contain the following information: Identification of the product; lot number/ subcodes, as applicable; quantity; date placed on hold; reason for hold; who placed the product on hold (contractor or GQAR); location and/or hold tag number; date released from hold; who released the product; and, the final disposition of the product. This is a quality history record that needs to be retained for the period indicated in the contract.

D. Does the QSP identify the person (maybe different positions) with the authority for the release of items placed on hold and include a procedure for the review and authority for the disposition of nonconforming items found during any stage of the process (receipt, storage, production, assembly, end item, shipment, etc.)?

SECTION V Continued

	Max Points	Assigned

E. Does the procedure indicate that the Government must approve rework procedures or plans and reworked product must be inspected according to Government approved procedures (as indicated in the contract) if the contractor opts to rework nonconforming product?

F. **Disposal of Product Intended, Produced or Manufactured for the U.S. Government thru Commercial Channels:** Does the QSP include a procedure that indicates the steps to be taken by the contractor if they decide to donate, sell or dispose in commercial channels of any end item or any part of it intended, produced or manufactured for the U.S. Government? As a minimum, the procedure must include the following: Steps taken for the removal/obliteration/wipe-out from a product and it's packing and packaging, any markings, symbols, or other representation that the end item or any part of it was intended, produced or manufactured for the U.S. Government; identify the person (by position) responsible for verifying this action; identify the form/ report used to record the action taken (identifying product, lot/subcode, quantity produced, quantity donated/sold/ disposed of by lot/subcode, the reason for this action, etc.) and; the procedure must also indicate that the In-Plant Government QAR shall be notified prior to such action taking place.

AREA 5. FOOD SECURITY: Due to the increase risk for the potential of intentional food tampering the QSP shall describe (in general terms) the types of safekeeping measures that are taken or will be taken to protect the food intended for the military. The QSP should include preventive steps taken to safeguard product from intentional tampering/contamination during all stages of receipt, production, storage, assembly, delivery, and shipment. **NOTE: <u>Do not send your security plan because this may compromise the security of your facility.</u>** If a Food Security survey/questionnaire (if required by the contract) was previously submitted (to a different DSCP office, not DSCP-HROS) omit the questions in this area, and only identify the DSCP office, name of the person the plan was submitted to, and date of submittal. **NOTE:** Points **will not** be deducted for providing a negative response. However, points **will be** deducted for not answering (yes, no, N/A) a question.

A. Personnel: Does the QSP address the following

1. Does the QSP include a policy statement concerning top management support for product security and the integrity of food supplies?

2. Does the QSP identifies the manager responsible for reviewing the adequacy of the security of the facility, safeguarding the product and integrity of food supplies, and overall review of the organizational corporate security plan for determining whether a private security firm is needed to assess or reduce corporate risk?

3. Employees: Are background checks conducted? Are jobs and references verified? Who ensure background checks are maintained up to date? How often?

4. How are visitor's movement controlled to prevent them from accessing restricted areas?

5. Are truck drivers required to possess and present upon request adequate identification prior to entering the facility/gate?

B. **Incoming Shipments:**

1. How do they verify that all deliveries are scheduled and approved prior to entering the facility?

2. How do they ensure open trucks are not left unattended?

3. Delivery vehicles: Are security seals properly placed on delivery vehicles and registered/ logged in per delivery? Are seal numbers recorded on the Bill of Lading? Is the seal numbers controlled/verified and inspected for possible tampering of shipment?

4. Does the QSP include a procedure for inspecting for evidence of intentional tampering? The procedure must ensure that product/ingredients entering the facility are safe for consumption/use (boxes, bins, packaging material that will come in direct contact with product, ingredients, etc)?

5. Are receipt inspectors trained to look for obvious signs of shipment and/or product tampering and to verify the integrity of incoming shipments and products during their receipt inspection?

SECTION V Continued

	Max Points	Assigned
C. **Outgoing Shipments:**		
1. Is advance notification provided to all destinations for outgoing shipments?		
2. How do they ensure open trucks are not left unattended during loading?		
3. Delivery vehicles: Are trucks sealed immediately after loading? Are security seals properly placed on delivery vehicles and registered/logged in per delivery? Are seal numbers recorded on the Bill of Lading? Is a record maintained of all seal numbers?		
4. Are truck drivers provided with communication devices and emergency telephone numbers in the event of an emergency?		
D. **Production Facilities, Storage Areas/Warehouses, and Surrounding Areas of the Facility:** Does the QSP addresses the following:		
1. Is the procedure for storing product adequate to control access and minimize or eliminate the possibility of product adulteration/tampering? NOTE: The QSP must identify **all** storage facilities used to store ingredients/products intended for the military.		
2. How are the facilities protected from unauthorized entry during operation and non-operational hours: Are the facilities fenced? Locking devices? Alarms? Lighting? Surveillance cameras? What areas?		
E. **Communication:**		
1. Does the contractor ensures employees and truck drivers keep a low profile and not share information regarding: quantities, criticality of products being produced for the military, customer routes, and/or discussed on a need-to know basis only?		
2. Is there a procedure for employees/truck drivers to report suspicious activity and informed that product security and integrity of food supplies should not be taken lightly that and that any instances of suspected adulteration or tampering must be reported immediately. Note: A documented reporting procedure must be in-place and all employees must be informed of this procedure. Communication must include management personnel, local authorities, DSCP/cognizant contracting officer, and/or field offices. It is imperative that all employees are reminded that timely notification is essential to any perceived or potential threat.		
F. **Subcontractors/Suppliers Food Security:**		
1. Does the QSP indicate how the contractor ensures suppliers/subcontractors have instituted some type of food security or safekeeping measures to protect the ingredients to be used in the production of products intended for the military?		
2. Does the QSP define the type and extent of control exercised by the contractor over their suppliers regarding food security and safekeeping measures that should be taken to protect the ingredients to be used in the production of products intended for the military?		
TOTAL POINTS: 100		

SECTION V AUDITOR'S NOTES (justification/comments must be provided for areas/questions found marginally acceptable, unacceptable or not addressed)

SECTION VI
CONTRACT REVIEW, PURCHASING AND CONTROL
OF CUSTOMER-SUPPLIED PRODUCT

REFERENCE: Contract TDP Section E, MPC Clause, SPC QAP, Specific Product Specifications or Commercial Item Descriptions, and ISO 9001:2000 (4.2.3, 4.2.4, 7.2, 7.2.3, 7.4, 7.4.1, 7.4.2, 7.4.3, and 7.5.4) and ANSI/ASQC Z1.4.

	Max Points	Assigned

AREA 1. CONTRACT REVIEW (ISO 7.2): The contractor must establish and maintain documented procedures for contract reviews, document, data and record control and for the coordination of these activities.

A. REVIEW:

1. Does the QSP identify company's manager or personnel responsible for contract reviews (before submission or acceptance of a contract or order)?

2. Does the QSP indicate how contract reviews are performed?

B. AMENDMENT TO A CONTRACT (ISO 7.2.3): Does the QSP indicate how amendments to a contract are transferred and communicated to the functions concerned within the organization (to include the Government QAR) and external functions (subcontractors and suppliers) as applicable?

C. RECORDS (ISO 4.2.3 and 4.2.4): Does the QSP indicate who and where (location) records of contracts' reviews will be maintained?

AREA 2. PURCHASING (ISO 7.4): The contractor shall establish and maintain documented procedures to ensure that purchased ingredients or components conform to contractor's specified requirements and the contract requirements.

A. EVALUATION OF SUBCONTRACTORS/SUPPLIERS (ISO 7.4.1):

1. Does the QSP indicate how suppliers/subcontractors are selected and evaluated (criteria used, product or on-site audits conducted, etc.)?

2. Does the QSP define the type and extent of control exercised by the contractor over subcontractors?

3. Does the QSP indicate what subcontractors are required to have a documented QSP, require Government source inspection, and/or any other specific quality assurance requirement (such as SPC)?

B. PURCHASING DATA (ISO 7.4.2):

1. **Master List:** The contractor must develop and submit with the QSP a list of all ingredients/ components/materials used in the production/assembly of products intended for the Government. This list must identify the following for each ingredient/product/material (may be identify by grouping if same requirement): Paperwork/documents that are required to be received with each shipment (Certificate of Conformance, Certificate of Analysis, USDA Grading Certificate, Supplier Certification, Bill of Lading, Letter of Guarantee, etc.). If a COC covers several shipments (or entire contract), the period covered must be identified by the applicable item. The GQAR and receipt inspectors must be provided with a copy of this list. **NOTE: The entire section will be rated unacceptable if this information is not provided.**

2. Does the QSP indicate how the contractor conveys purchase requirements to suppliers for components and materials requiring Government source inspection, physical or chemical characteristic testing, requirements for approval or qualification of ingredient or product, or other specific requirements?

3. Does the QSP identify the steps taken if a subcontractor is required to submit a documented QSP to the contractor or DSCP?

4. Does the QSP include a procedure for the review and approval of purchasing documents for the specified ingredient/product prior to release?

	Max Points	Assigned
C. VERIFICATION OF PURCHASED PRODUCT (ISO 7.4.3):		
1. Does the QSP indicate the steps to be taken if the contractor requires Government verification of ingredient or product conformance at source (the subcontractor's plant) or if an ingredient or product requires Government source inspection??		
2. Does the QSP indicate that the Government has the right to verify, at the subcontractor's facilities, that subcontracted product and/or quality system conforms to contractual requirements?		
3. Does the QSP indicate or include a procedure to ensure that all inspection documents and referenced data for purchased supplies that require Government source inspection or have particular requirement to be reviewed for accuracy and maintained on file for review by the Government QAR?		
4. Does the QSP stipulate that the Government QAR shall be provided copies of Government source inspection documents (grading certificates, laboratory analyses, etc.) and purchasing documents for other products for review within the contractor's facility or for verification at the supplier/ subcontractor's facility, as deemed necessary by the Government?		
AREA 3. CONTROL OF CUSTOMER-SUPPLIED PRODUCT (ISO 7.5.4):		
A. Does the QSP contain a procedure for the inspection, storage, and maintenance of Government-furnished material (GFM) provided for incorporation in the assembly of operational rations or to use in related activities?		
B. Does the QSP contain procedures for the recording and reporting of GFM that is lost, damaged or otherwise unsuitable for use by the Government?		
TOTAL POINTS:	**100**	

SECTION VI AUDITOR'S NOTES (justification/comments must be provided for areas/questions found marginally acceptable, unacceptable or not addressed)

SECTION VII
RECEIPT INSPECTION AND TESTING

REFERENCE: Contract TDP Section E, MPC Clause, SPC QAP, Specific Product Specifications or Commercial Item Descriptions, and ISO 9001:2000 (4.2.3, 4.2.4, 7.4.3, 7.5.3, and 8.2.4) and ANSI/ASQC Z1.4.

	Max Points	Assigned
GENERAL: The contractor shall establish and maintain documented procedures for receipt inspection and testing activities to verify that the requirements for the product or ingredient (contractor's specified requirements and contract requirements) are met. The required inspection and testing and the records to be established, shall be detailed in the QSP. A. Does the QSP include clear and complete receipt inspection procedures: Sampling plan (acceptance/rejection criteria) and what constitutes a nonconformance for items that require receipt inspection in accordance with contractor's specified requirements or the contract requirements? B. **Master List:** The contractor must develop and submit with the QSP a master list of all ingredients/ components/materials used in the production/assembly of products intended for the Government. Is the list included with the QSP? **NOTE:** The list or the procedures must identify and clearly define the following for each ingredient/product/ material (may be done by groupings if same requirement): How the lot size is expressed for each item or group of items received (e.g. number of boxes, cans, pounds, yards, patties, steaks, pouches, containers received, etc.); the sample unit (e.g., the sample unit may consist of one or more units of product drawn from a lot for inspection purposes for each group of items received - number of boxes, cans, pounds, rolls, yards, pouches, one pound/one cup of product from large containers, 2 steaks/patties per sample unit/box, etc.); how samples will be selected (for example random throughout the shipment, selected proportionally from each supplier's lot/subcode/date of pack received, etc.); type of inspection (paperwork/certification verification with items received, visual/non destructive, and/or destructive inspection/testing, etc.); number of temperatures taken and temperature requirements for frozen/chill products/ingredients; acceptance/rejection level; paperwork/documentation that is required to be received with the shipment; and, the coordination protocol when a nonconforming item is received and/or required paperwork is not received with the shipment. **NOTE:** The entire Section will be rated unacceptable if this information is not provided. C. Does the QSP include or reference working instructions and forms to be used by contractor personnel to ensure required information is properly documented and records are maintained? D. Does the QSP contain a program that ensures only contractual inspection procedures (or Government approved alternative procedures as detailed in the contractor's QSP) are used for all receipt inspections? E. Does the procedure ensure incoming product or ingredients are not used or processed until it has been inspected or otherwise verified as conforming to specified requirements? F. Is the amount and nature of receiving inspection consistent with the amount of control exercised at the subcontractor's plant and the recorded evidence of conformance provided (Government inspection at subcontractor facility, USDA grading certificates, certificate of analysis, etc.)? G. Does the QSP include a procedure positively identifying and recording product or ingredients released for urgent production purposes prior to verification to permit immediate recall in the event of nonconformance to specified requirements? Does the procedure indicate that the Government QAR will be notify before such action takes place?		
TOTAL POINTS:	**100**	

SECTION VII AUDITOR'S NOTES (justification/comments must be provided for areas/questions found marginally acceptable, unacceptable or not addressed)

SECTION VIII
IN-PROCESS AND PROCESS INSPECTION AND TESTING

REFERENCE: Contract TDP Section E, MPC Clause, SPC QAP, Specific Product Specifications or Commercial Item Descriptions, and ISO 9001:2000 (4.2.2, 4.2.3, 4.2.4, 5.2, 5.3, 5.5.1, 6.2.2, 7.1, 7.4, 7.5, 7.5.1, 7.5.2, 7.5.3, 7.6, 8.2.2, 8.2.3, 8.2.4 and 8.4) ,ANSI/ASQC Z1.4, and ANSI/ASQC Z1.1thru ANSI/ASQC Z1.4.

	Max Points	Assigned

GENERAL: The contractor shall establish and maintain documented procedures for all in-process and process control inspection and testing activities to verify that the specified requirements for the product (cited in contractor's QSP and the contract) are met. The required inspection and testing and the records to be established, shall be detailed in the QSP procedures.

AREA 1. PROCEDURES: The QSP must include procedures that describe the production/assembly operations and how the contractor ensures these are carried out under control conditions to assure that product characteristics and criteria specified in the contract are achieved and maintained in the finished product (end item).

A. Does the QSP identifies and defines each in-process control point (IPCP) and/or process control point (PCP) in sequence in relation to the production, subassembly/assembly flow or chain of events (from weighing/mixing/batching of ingredients, packaging, to final product)? **NOTE: The entire section will be rated unacceptable if the following information is not provided.**

1. Are the location of each IPCP and PCP identified? Is the location appropriate to control those factors that may have an effect on the safety, quality or conformance of the produced item (end item)?

2. Is each characteristic and/or process to be controlled and the type of control technique (manufacturing process control or statistical process control technique) to be used to control each characteristic or process identified at each IPCP or PCP?

3. Are the control measures and criteria for action (acceptable/unacceptable) for each characteristic tested/examined at each IPCP and PCP Identified? Does the QSP indicates how and when are the following established (as applicable for SPC or MPC techniques): Upper control limits (UCL) and lower control limits (LCL); upper specification limits (USL) and lower specification limits (LSL); and action limits and/or action number for reaction.

4. How, when and why are the above limits adjusted?

5. Is the sampling plan fully explained? The type and amount of inspection for each characteristic or process to be checked/tested at each IPCP and PCP; location of sample selection; number of samples to be selected; frequency of testing (batch, subcode, time frame, etc.); and criteria for subgroup sample size, etc.

6. Does the procedure identifies/defines the tests used to identify "out-of-control" processes?

7. Is the criteria and frequency for verifying control of the process by QA identified?.

8. How inspection results are documented (reference forms/ reports used)?

9. Is the following identified at each IPCP and PCP: Who performs inspections/tests; who records inspection or test results and/or plots data on control charts; who is responsible for identifying out-of-control situations; who initiates corrective actions, and who decides upon and implements corrective actions? NOTE: Maybe addressed in Section XII and should be addressed on several levels, that is, operator, supervisory, management.

B. Is sampling appropriate to production rate to identify variation in the process?

C. Is the following identified for each IPCP and PCP: Inspection equipment and instruments used; documents and supplies needed; and, the work environment (lighting, temperature, etc.) under which specific tests/ inspections will be conducted.

	Max Points	Assigned

D. Does the QSP inspection procedures ensure only contractual procedures or Government approved alternative procedures are used to conduct in-process inspections and testing?

E. Does the QSP include procedures and reference or include working instructions for those inspections (examinations or tests) performed during production on product characteristics that cannot be inspected at a later stage? If in-process control of ingredients, product or material is not practical, the procedure needs to identify alternative controls used (i.e., monitoring processing methods, equipment, or personnel).

F. Control of machines and product: How does MPC/SPC influence control? Is a mechanism for feedback from SPC/MPC data evaluation for the control of machines and product delineated?

G. Are the type and extent of reliance on computer hardware and software used for SPC or MPC explained in the QSP?

AREA 2. GENERAL SPC REQUIREMENTS (ISO 5.2 and 5.3): The contractor shall establish and maintain documented procedures to implement and control the application of statistical techniques identified in the contract SPC QAP or if SPC techniques are part of the contractor's quality system. The required inspection and testing, controls, and the records to be established, shall be detailed in the procedures.

A. Does the QSP identify the need for statistical techniques required for establishing, controlling, and verifying process capabilities and product characteristics? If SPC techniques are required by the contract to control a specific process or characteristic but the contractor deems SPC inappropriate, does the QSP identify alternative techniques and controls (MPC) for each process or characteristic identified in the contract to be controlled using SPC?

B. Did the Government approve alternative techniques and controls? Are these techniques and controls clearly detailed above (Area 1)? NOTE: The contractor shall identify the characteristics or processes required to be controlled using SPC techniques and indicate that MPC techniques will be used.

C. Statistical Analyses: The contractor must manage and improve process performance by conducting statistical analyses (using pareto charts at a minimum) using SPC or MPC data collected at each IPCP and PCP for those characteristics requiring control, having an effect on the safety and/or the quality of the produced item (end item), the defects from previous production, and/or projection of potential defects in future production to discern the vital few and repetitive type failures from the trivial many. At a minimum, the contractor shall identify (using SPC or MPC data collected):

1. How (by process, characteristic, item, etc) pareto analyses will be conducted?

2. Is the minimum frequency to conduct Pareto analyses identified? Pareto analyses should be performed at least quarterly by item and characteristic identified in the contract, if SPC is contractually required.

D. The following shall be addressed as a minimum if SPC techniques are deemed appropriate to control the process or SPC is contractually required:

1. Does the QSP provide a list or identifies the references used as guidance for the SPC procedures and techniques described in the QSP? Minimum criteria are established in ANSI Z1.1, Z1.2, and Z1.3/ASQC B1, B2 and B3. Alternate SPC techniques such as short run methods are also allowed where applicable.

2. Are the characteristics or process to be controlled by SPC and operations where SPC will be implemented identified?

SECTION VIII Continued

	Max Points	Assigned
3. Process capability studies: Process capability studies should be conducted to determine the relationship of the natural manufacturing variability to the specified tolerance for each characteristic specified. The following should be addressed: When are studies performed in relation to award of a contract; criterion for study explained; definition of poor and marginal capability and the policy when capability is determined to be poor or marginal; and analysis of statistical distributions (that is, who, what, when, and how) needs to be explained in detail if SPC techniques are used. 4. Control Chart Policy (for each identified characteristic or process): Types of charts used and pertinent facts to be recorded on control charts should be delineated for major factors of assignable cause: Raw materials, methodology, personnel (inspection and production), equipment, environment, measurements, etc.		
TOTAL POINTS:	**100**	

SECTION VIII AUDITOR'S NOTES (justification/comments must be provided for areas/questions found marginally acceptable, unacceptable or not addressed)

SECTION IX
REGULATORY CONTROLS

REFERENCE: Contract TDP Section E, MPC Clause, SPC QAP, ISO 9001:2000 (6.3, 6.4, and 7.2), Specific Product Specifications or Commercial item Descriptions, applicable Code of Federal Regulations (CFR) and or other regulations.

	Max Points	Assigned

GENERAL: The supplier shall establish and maintain documented procedures for complying with regulatory requirements cited in the contract or other regulatory requirements applicable to the plant's operation. The required inspection and testing, controls, and the records to be established shall be detailed in the QSP procedures.

AREA 1. GENERAL REGULATORY REQUIREMENTS (ISO 7.2):

A. Does the QSP identify the regulatory requirements applicable to the plant's operations and products produced in the plant (applicable CFRs, contract pest management and sanitation requirements, and approval of plant by applicable regulatory agency/VETCOM, etc.)? **NOTE**: All food plants, at a minimum, require CFR Title 21, Chapter 1, PART 110 Current Good Manufacturing Practices in Manufacturing, Packaging or Holding Human Food.

B. Does the QSP include procedures and reference and/or include working instructions and forms used to monitor implementation and compliance of the following activities (if applicable to the plant and the products produced): (1) Review of operating process schedules and process schedules filed with the regulatory agencies; (2) HACCP plan (3) Partial Quality Control/Total Quality Control plans filed with the applicable regulatory agency (4) review of qualifications and training records of personnel performing activities or supervising retort area (5) review of pre-retort process controls (6) documentation of monitoring and control of critical factors cited in the process schedules, for example - maximum filled weight, maximum pouch/tray thickness, maximum residual gas, ingredient pre-batch hydration, slice thickness, viscosity, container orientation, product formulation and preparation procedures consistent with those indicated in the process schedule, etc. (7) filling and sealing operation and control of the two-hour limit from filling and sealing to retort process (8) application of heat sensitive tape to containers/retort carts prior to retort and verification after processing/post retort color change (9) control of retorted and un-retorted traffic (10) control/monitoring of processing operation (11) recycled/reused cooling water system and cooling water treatment - frequency of monitoring, treating, and documentation of results (12) control and review of incubator time and temperature (13) control of incubation samples: recording of in-out dates, daily monitoring of samples, and results of incubation (14) control and review of retort records (15) documentation of problems and actions taken to correct and prevent the problems identified (16) documentation and coordination of process deviations and final action taken (17) etc.

C. Does the QSP identifies the steps to be taken to comply with each of the regulatory requirements applicable to the facility and how the contractor ensures required information is properly documented and that records are maintained as required by the contract and/or the regulatory agencies?

D. Sanitation requirements: Does the QSP indicate if the facility (facilities) is currently listed in the Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement (published by the US Army Veterinary Command)? The information included must be verified with the DSCP-HR' Quality/Technical Manager.

For what products? _____

When was the last inspection conducted? _____

AREA 2. INTEGRATED PEST MANAGEMENT PROGRAM (ISO 6.3 and 6.4): This area is addressed separately under the IPM Program. The information included must be verified with the DSCP-HR' Quality/Technical Manager. As a minimum the QSP must include the following:

A. Date of the IPM Master Program:_____ Renewal Date:_____

Date evaluated:_____ Is the program acceptable? _____

IX Continued

	Max Points	Assigned
B. Current Pest Management Facility Map included? In order for the map to be acceptable the rodent and insect traps must be numbered/identified. **NOTE:** If more than one facility, a map for each facility must be included. Trap locations (at each facility) must also be physically and prominently marked/labeled with the applicable trap number in case a trap is inadvertently moved (facility trap location and trap number must correlate with trap number and location identified in the facility map). C. Does the QSP identify the minimum frequency to check/service the traps (by company personnel and contracted service)?		
TOTAL POINTS:	**100**	

SECTION IX AUDITOR'S NOTES (justification/comments must be provided for areas/questions found marginally acceptable, unacceptable or not addressed)

SECTION X
END ITEM INSPECTION AND TESTING

REFERENCE: Contract TDP Section E, MPC Clause, SPC QAP, Specific Product Specifications or Commercial Item Descriptions, ISO 9001:2000 (4.2.3, 4.2.4, 7.5.3, and 8.2.4) and ANSI/ASQC Z1.4.

	Max Points	Assigned
GENERAL: The contractor shall establish and maintain documented procedures for end item inspection and testing activities to verify that the specified contract requirements for the end item are met. The required inspection and testing, and the records to be established shall be detailed in the QSP.		
A. Does the QSP procedures ensure only specified end item requirements/inspection procedures cited in the contractual item documents/TDP are used during end item inspection? If the inspection procedures and requirements cited in the product specification are used (there is no need to re-write the inspection/test/sampling procedure requirements cited in the product document), the contractor may include the following statement (and omit answering B): "End item inspection and testing will be conducted in strict accordance to the product specification/CID/contract requirements using the _____ sampling method. No product/samples will be inspected until the entire lot is completed and the total number of samples needed for an inspection/test have been selected."		
B. Does the QSP provide clear and complete end item inspection procedures to ensure that the end item/finished product is inspected in accordance with the sampling plan (inspection level and acceptable quality levels) and specific inspection/test methods cited in the product document (specification/PCR/CID) and/or as otherwise indicated in the contract?		
C. End item Sample selection and inspection. Only two methods are contractually authorized for operational rations for sample selection and inspection: Samples can be selected using stationary sampling (samples are randomly selected after lot is completed) or stratified sampling (samples are selected throughout the production day using a logical rationale, subode/time frame/batch, and set aside until the lot is completed). Under both methods samples **shall not** be inspected until the entire lot is completed. **The method selected must be clearly identified in the QSP.** If stratified sampling is selected, does the QSP clearly indicate rationale used to select samples and how many samples will be selected at one time?		
D. Does the QSP include or reference working instructions and forms used by contractor personnel to ensure all required information is properly documented and records are maintained?		
E. Evidence of product conformance: Does the QSP indicate that a copy of records or related documentation to substantiate product conformance to the QSP and the contract will be provided to the Government QAR for review prior to or simultaneously when an end item lot is presented for Government verification inspection? **NOTE**: Associated data and documentation shall include all specified inspections and tests conducted by the contractor: Receipt and in-process/process inspections and tests, analytical tests results (contractor and Government testing) rework/reinspection results, record of corrective and preventive actions taken at any stage of the process, end item inspection and testing, etc.		
TOTAL POINTS :	**100**	

SECTION X AUDITOR'S NOTES (justification/comments must be provided for areas/questions found marginally acceptable, unacceptable or not addressed)

SECTION XI
INTERNAL AUDITS

REFERENCE: Contract TDP Section E, MPC Clause, SPC QAP and ISO 9001:2000 (4.2.1, 4.2.3, 4.2.4, and 8.2.2)

	Max Points	Assigned
GENERAL: The contractor shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.		
AREA 1. AUDIT SCHEDULE (ISO 4.2.1 and 8.2.2):		
A. Does the QSP identify the basis or rationale used to schedule each area or activity to be audited (e.g., by criticality or importance of a specific area or activity that will have a definitive effect on the safety, quality or conformance of the end item)? Is the frequency for each area or activity to be audited identified?		
B. Does the QSP contain an internal quality audit schedule and identifies the frequency to audit the complete quality system? (The frequency to audit the complete system must not exceed the DSCP's minimum frequency of one year).		
C. Does the QSP indicate that a follow-up audit must be conducted to verify the implementation, compliance, and effectiveness of corrective action taken when deficiencies are noted by the internal auditor or during a DSCP/GQAR compliance audit (e.g., frequency of internal audits can be based on the criticality of the deficiency noted or the importance of a specific area/activity that will have a definite effect on the safety, quality or conformance of the finished product)?		
AREA 2. PERFORMANCE OF INTERNAL QUALITY AUDITS (ISO 8.2.2):		
A. Does the QSP identify personnel who will be responsible for the performance of quality audits?		
B. Does the QSP indicate that each area or activity audited will be carried out by personnel independent of those having direct responsibility for the area or activity being audited? NOTE: Follow-up audits **shall not** be conducted by personnel that took or is responsible for taking or implementing a corrective action due to a deficiency noted in the initial audit.		
AREA 3. DOCUMENTATION AND REPORTING OF AUDIT RESULTS (ISO 4.2.3 and 4.2.4):		
A. Does the QSP include or reference the documentation and forms used to record audit results?		
B. Does the QSP identify personnel having responsibility for each area or activity to be audited?		
C. Does the QSP specify that audit results will be reported to the management personnel having responsibility for the area or activity audited? Does the QSP also stipulate that these management personnel shall also be responsible to take timely corrective action on deficiencies found during the audit (based on the criticality of the deficiency and the suspense date provided by the auditor conducting the audit)?		
D. Does the QSP describe how management uses audit results during management reviews or for continuous improvement?		
E. Does the QSP identify the guidance or reference document used to develop and perform internal audits?		
TOTAL POINTS:	**100**	

SECTION XI AUDITOR'S NOTES (justification/comments must be provided for areas/questions found marginally acceptable, unacceptable or not addressed)

SECTION XII
CORRECTIVE AND PREVENTIVE ACTION

REFERENCE: Contract TDP Section E, MPC Clause, SPC QAP, and ISO 9001:2000 (8.5.2 and 8.5.3)

	Max Points	Assigned
GENERAL: The contractor must include documented procedures for implementing corrective and preventive action. Any corrective action or preventive action procedure to be taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered. A copy of all corrective and preventive actions taken must be provided to the Government QAR when an end item lot is submitted for Government verification inspection and to DSCP when a request for reinspection, waiver, deviation or rework is requested.		
AREA 1. CORRECTIVE ACTION (ISO 8.5.2): The QSP must include documented procedures for the following at a minimum:		
A. Does the QSP include a procedure for the effective handling of customer complaints and reports of nonconformance?		
B. Does the QSP include a procedure for the investigation of the cause of nonconformances relating to product, process, and quality system, and recording the results of the investigation such as:		
1. Corrective and preventive action and failure analysis:		
2. How are investigations handled (by one person/team/review board)?		
3. Are responsibilities for action addressed for: Inspectors, operators, supervisors and management?		
C. Does the QSP include a procedure for the determination of the corrective action needed to eliminate the cause of the nonconformance?		
D. Does the QSP include a procedure for the application of controls to ensure that corrective action is taken and is effective?		
AREA 2. PREVENTIVE ACTION (ISO 8.5.3): The QSP must include documented procedures for the following at a minimum:		
A. Does the QSP include a procedure for the use of appropriate sources of information such as processes and work operations which will affect product quality, audit results, quality records, and customer complaints to detect, analyze, and eliminate potential causes of nonconformances?		
B. Does the QSP include a procedure for the determination of the steps needed to deal with problems /deficiencies requiring preventive action?		
C. Does the QSP include a procedure for the initiation of preventive action and application of controls to ensure that it is effective?		
D. Does the QSP include a procedure for the confirmation that relevant information on actions taken is submitted for management review?		
TOTAL POINTS:	**100**	

SECTION XII AUDITOR'S NOTES (justification/comments must be provided for areas/questions found marginally acceptable, unacceptable or not addressed)

SECTION XIII
IMPROVEMENT

REFERENCE: REFERENCE: Contract TDP Section E (SPC QAP), and ISO 9001:2000 (5.2, 8.2.1,8.4, 8.5 and 8.5.1)

	Max Points	Assigned
GENERAL: The total cost of quality normally consists of prevention, appraisal, and failure costs of an organization. The true value of knowing what an organization's cost of quality is for the most part immeasurable. However, all successful businesses routinely incorporate the function of computing the cost of quality as one of their main business operations. Computing the cost of quality allows an organization to properly budget for all necessary quality activities required by the contract or the contractor's QSP requirements. Additionally, it provides an organization the ability to appropriately allocate the resources required to effect continuous improvement in their day-to-day operations that impact the quality of the goods they provide to their customers. Contractors may include information concerning their use of cost of quality models in their day-to-day operations to continuously evaluate and improve their quality system and the products produced.		
AREA I. CUSTOMER SATISFACTION (ISO 5.2 and 8.2.1): As one of the measurements of the performance of the QSP and the quality system implemented, the supplier shall monitor information relating to customer perception as to whether the supplier is meeting or has met customer requirements. The methods for obtaining and using information shall be determined. Does the QSP indicates how the supplier determines, obtains information, and measures customer satisfaction and compliance to customer requirements?		
AREA 2. IMPROVEMENT (ISO 8.5):		
A. Continual improvement (ISO 8.4 and 8.5.1): The supplier shall continually improved the effectiveness of the QSP and the system implemented through the use of the quality policy, quality objectives, internal and external audit results, analysis of data, corrective and preventive actions, customer feedback, and management reviews.		
1. Management reviews: Does the QSP indicate how management reviews are used for continual improvement?		
2. Top management support: Does the QSP indicate that full support will be provided to the internal auditor and the manager who is responsible for reviewing the quality system to ensure its continuing suitability and effectiveness in satisfying the requirements of the quality standard selected, the supplier's stated quality policy and objectives, and the requirements of DSCP contracts? Although teamwork and cooperation is emphasized, to avoid conflicting priorities quality personnel should not be placed under the direct supervision of production personnel.		
B. The cost of quality:		
1. Does the QSP identify how the cost of quality is computed? Suppliers can include information concerning their use of cost of quality models in their day-to-day operations to continuously evaluate and improve their quality system, indicate their active participation in the Government Value Engineering Change Proposal Program (VECP), the DSCP-HROS' Quality Improvement Initiate Report Program, or other continuous improvement programs, etc.		
2. Does the QSP identify how the failure cost (rework, scrap rate, reinspections, retesting, etc.) is computed?		
TOTAL POINTS:	**100**	

SECTION XIII AUDITOR'S NOTES (justification/comments must be provided for areas/questions found marginally acceptable, unacceptable or not addressed)

REFERENCES

ANSI/ISO/ASQC A3, Quality Systems Terminology. Milwaukee, WI: American Society of Quality Control.

ANSI/NCSL Z540-1 Standards for Calibration Systems. Milwaukee, WI: American Society of Quality Control.

ANSI/ASQC Q10011-1, Q10011-2, and Q10011-3, Guidelines for Auditing Quality Systems. Milwaukee, WI: American Society of Quality Control.

ANSI Z1.1, Z1.2, AND Z1.3/ASQC B1, B2, and B3 American National Standard: Guide for Quality Control Charts, Control Chart Method of Analyzing Data, Control Chart Method of Controlling Quality During Production. Milwaukee, WI: American Society of Quality Control.

ANSI/ASQC Z1.4, American National Standard: Sampling Procedures and Tables for Inspection by Attributes. Milwaukee, WI: American Society of Quality Control.

ASTM D 5118/D5118M-95 Standard Practice for Fabrication of Fiberboard Shipping Boxes.

ASTM 1974 Standard Practice for Methods of Closing, Sealing, reinforcing Fiberboard Shipping Boxes.

CFR Title 21, Chapter 1, CFR, PART 110 Current Good Manufacturing Practices in Manufacturing, Packaging or Holding Human Food.

CFR Title 21, PART 113, SUBPART D (FDA Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers

CFR Title 9 USDA FSIS Canning Regulations and Canned Products PART 318 Subpart G (meat)/ Part 381 Subpart X (poultry) (poultry/meat are essentially identical).

Contract Technical Data Packages

DLAR MPC CLAUSE 52-246-9001- Manufacturing Process Controls and In-Process Inspections

DSCP Statistical Process Control Quality Assurance Provision

DSCP FORM 3507 Unit Loads: Preparation of Semi-perishable Subsistence Items.

DSCP FORM 3556: Markings: Instructions for Shipping Cases, Sacks, and Palletized/Containerized Loads of Perishable and Semi-Perishable Subsistence.

ISO 8402, Quality Management and Quality Assurance: Vocabulary. Geneva, Switzerland: International Organization for Standardization. Milwaukee, WI: American Society of Quality Control.

ISO/ANSI/ASQC 9000, Quality Management and Quality Assurance Standards: Guideline for Selection and Use.

ISO 10012-1, Quality Assurance Requirements: Measuring Equipment. Milwaukee, WI: American Society of Quality Control.

ISO/ANSI/ASQC Q9001: 2000, Quality Management Systems - Requirements. Milwaukee, WI: American Society of Quality Control.

USDA FILE CODE 125-A-1 US Standards for Condition of Food Containers.

APPENDIX A
QSP SUMMARY RATING SHEET

QSP SUMMARY RATING SHEET

GENERAL: After each section has been evaluated an overall evaluation of that section should be completed and a rating assigned (acceptable, marginal, or unacceptable). After all sections are evaluated an overall rating should be assigned to the QSP. An overall unacceptable rating to a section will deem the QSP unacceptable. Some subjectivity in developing an overall evaluation is inevitable. However, concise detailed statements should be included to substantiate the overall rating assigned to the QSP, specifically if a marginal or unacceptable rating is assigned. Professional expertise and judgment must be exercised to provide an accurate and objective evaluation. Every area of the QSP does not have to be acceptable for the section to be considered acceptable or marginal. Likewise, one area scored unacceptable does not necessarily means that the entire section or plan is unacceptable. The percentage of areas acceptable, marginal, and unacceptable should be computed for each section. The importance of each area or question within each section will determine the points assigned to each area or question. If clarification is needed concerning an area or section and in the evaluator's opinion the contractor can provide this information over the telephone (if no written modification to the QSP is necessary), the contractor should be contacted. If any section of the QSP is rated marginal, the evaluator must request that the section/area rated marginal be revised. A suspense date of 30 calendar days should be allocated for the contractor to revise the areas/sections rated marginal. The evaluator should continue working with the contractor until all sections of the QSP are rated acceptable.

AREA 1 COMPUTATION OF SECTION AND QSP RATING: An overall rating of unacceptable to a section will result in an unacceptable QSP rating. The maximum point assigned to each section is 100. The maximum points assigned to the QSP are 1300.

SECTION		**QSP**	
ACCEPTABLE	90>	ACCEPTABLE	1170>
MARGINAL	80>	MARGINAL	1040>
UNACCEPTABLE	80<	UNACCEPTABLE	1040<

	MAXIMUM POINTS	**POINTS ASSIGNED**	**RATING**
SECTION I	100		
SECTION II	100		
SECTION III	100		
SECTION IV	100		
SECTION V	100		
SECTION VI	100		
SECTION VII	100		
SECTION VIII	100		
SECTION IX	100		
SECTION X	100		
SECTION XI	100		
SECTION XII	100		
SECTION XIII	100		
TOTAL POINTS	**1300**	**TOTAL POINTS ASSIGNED:**	**QSP RATING:**

AREA 2 EVALUATOR'S COMMENTS/JUSTIFICATION FOR ASSIGNED RATING: Comments must be provided for each section, area or question rated unacceptable or marginally acceptable to allow the contractor the opportunity to improve the QSP.